K090055

OCT 2 7 2009

October 9, 2009

Section III – 510(k) 090055

Summary of Safety and Effectiveness

Submitter:

DPM USA Corp.
1460 NW 107 Ave Suite G
Miami, Florida 33172
Phone: 305-640-9894
Fax: 305-477-3206
Contact Person: George Echeverri

Summary Prepared Date: October 9, 2009

Device Name:

I. Trade Name- Elite Low Speed Air Motor with Elite "E" contra-angle, Medidental high speed handpiece
II. Common Name- Air-powered Low Speed Handpiece, E Type contra-angle, Air-powered High Speed Hanpiece
III. Classification Name- Handpiece, Air-Powered Dental
IV. Classification Number:21 CFR 872.4200
V. Product Code: EFB

Device for Which Substantial Equivalence is Claims:

1. High & Low Speed Handpiece, with E-Type contra-angle
2. 510 (k) 073652
3. Manufacture: NAKAMURA MAGNIFIER CO., LTD.

Device Description / Intended Use:

The Elite low speed air motor with Elite "E" contra-angle is to power various attachments which helps the dental clinician perform various dental procedures, removing carious material and excess filling material, cavity and crown preparation, root canal preparations, restoration and polishing teeth.

The Medidental high speed handpiece is an air-powered dental handpiece which helps the dental clinician perform various dental procedures such as removing carious material and excess filling material, cavity and crown preparation, root canal preparations, restoration and polishing teeth.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mr. George Echeverri
DPM USA Corporation
1460 NW 107 Avenue, Suite G
Miami, Florida 33172

OCT 27 2009

Re: K090055
Trade/Device Name: Elite Low Speed Air Motor with Elite "E" Contra-angle, Medidental High Speed Handpiece
Regulation Number: 21CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFA
Dated: October 9, 2009
Received: October 13, 2009

Dear Mr. Echeverri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

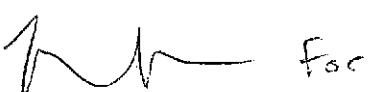
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if know): 090055

Device Name: Elite Low Speed Air Motor with Elite "E" contra-angle, Medidental high speed handpiece

Indications for Use:

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The Medidental high speed handpiece is an air-powered dental handpiece which helps the dental clinician perform various dental procedures such as removing carious material and excess filling material, cavity and crown preparation, root canal preparations, restoration and polishing teeth.

Prescription Use___X_____ AND/OR Over-The-Counter Use_____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
vision of Anesthesiology, General Hospital
iection Control, Dental Devices

10(k) Number: K090055